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DEC 19 2012

SECTION 9

510(k) Summary

Neurodyn Powered Muscle Stimulator
Neurodyn Aussie Muscle Stimulator

510 (k) Number: K121369

Date of Submission December 13, 2012

Submitter:
IBRAMED EQUIPAMENTOS MEDICOS
Avenida Dr. Carlos Burgos 2800
Amparo – Sao Paulo – Brasil

TEL – 5519-3817-9633
FAX – 5519-7816-7980

Official Contact:
Lilian Llull
TechLink International Consulting
18851 NE 29th Avenue
Suite 720
Aventura, FL 33180

TEL – (305) 206-6777
FAX – (305) 377-0088

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510 (k) premarket notification is in accordance with 21 CFR 807.87.

Common (Standard) Name: Powered Muscle Stimulator
Trade Name: Neurodyn Powered Muscle Stimulator
Neurodyn Aussie Powered Muscle Stimulator

Regulation Number & Product Codes:
GZJ - 21 CFR 882.5890-Transcutaneous electrical nerve stimulator for pain relief
IPF - 21 CFR 890.5850-Powered muscle stimulator
LIH - Interferential Current Therapy-Pre-amendment
GZI- 21 CFR 882.5810-External functional neuromuscular stimulator

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DEVICE CLASS II

Specifications - Both devices were designed according to Existing Technical Standards for the Development of Medical Devices (NBR NBR IEC 60601-1 IEC 60601-1-2 and IEC 60601-2-10 NBR).

Predicate Device Identification:

Chattanooga Vectra Genisys K031077

Predicate devices had been submitted and cleared by 510(k) for the same intended uses and indications.

Device Description

Neurodyn and Neurodyn Aussie Neuromuscular Stimulators are intended for the treatment of, relief of chronic (long term) intractable pain as adjunctive treatment of post-surgical and post-traumatic acute pain. Both devices have the same intended uses and incorporate the same technologies as the predicate the Vectra Genisys K031077. The Neurodyn Muscle Stimulator is a programmable device. It comes equipped with 5 preset clinical programs along with 10 user protocols. The user programs are adjustable and can be changed according to the patient's needs, doctor's recommendations and prescription settings.

The Neurodyn Aussie Muscle Stimulator has four output channels with independent intensity controls. Thus, four different areas can be stimulated separately or together during a therapy session. It is adjustable and can be changed according to the patient's needs, doctor's recommendations and prescription settings. It generates the medium frequency alternate current (MFAC), burst modulated alternating current (Aussie)- type of sinusoidal current with a frequency carrying 1,000 Hz or 4,000 Hz and a burst duration of 4 ms or 2 ms, modulated in pulse trains (bursts) with a variable frequency from 1 to 120Hz.

Indications for Use

As a TENS device:
Symptomatic relief of chronic (long term) intractable pain
Symptomatic relief of post-traumatic acute pain and post-surgical acute pain

As an Interferential and Premodulated device:
Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain

As a Russian device: Temporary relaxation of muscle spasms
Prevention or retardation of disuse atrophy in post-injury type conditions
Increase local blood circulation

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Muscle re-education
Maintaining or increasing range of motion

As an Burst modulated alternaing current (Aussie) device:
Temporary relaxation of muscle spasms
Prevention or retardation of disuse atrophy in post-injury type conditions
Increase local blood circulation
Muscle re-education
Maintaining or increasing range of motion

As a Microcurrent device:
Symptomatic relief of chronic intractable pain
Symptomatic relief of post-traumatic acute pain and post-surgical acute pain

Essential Performance

Neurodyn Muscle Stimulator produces the following currents:
Russian / Aussie / Interferential / Tens / Premodulated / Microcurrent

Neurodyn Aussie Muscle Stimulator produces the burst modulated alternating current (Aussie) medium frequency alternate current. The current intensity required for treatment depends on the patient's sensitivity. The treatment should be started with minimum levels of intensity with gradual increase until the patient achieves the full effect of the treatment.

Electrodes

Electrodes used are Axelgaard K970426. The minimal size of the electrode that can used with the Neurodyn and Neurodyn Aussie is $25cm^2$.

Patient Cables

Utilizes shrouded connectors to meet Lead Wire Connectors Safety Requirements IEC-60601-1 Sub clause 66-3 -c -according to 21 CFR 898. They are designed to be 4.5 feet (1.5 meters) away from the patient. The connector cables are designed to comply with subclause 56.3 (c) of the following standard:
International Electrotechnical Commission (IEC)
60601-1: Medical Electrical Equipment
60601-1 (1988) Part 1: General requirements for safety
Amendment No. 1 (1991)
Amendment No. 2 (1995)

Declaration of Conformity

This device has been assessed and found compliant. It upholds the highest safety and effectiveness standards.

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Summary of Safety and Effectiveness

- The Neurodyn and Neurodyn Aussie Muscle Stimulators are substantially equivalent to the Vetra Genisys K031077 manufactured by Chattanooga. All three devices claim similar Indications for Use and Device Characteristics in technological design and materials.
- The Neurodyn and Neurodyn Aussie Muscle Stimulators do not raise any new issues of Safety and Effectiveness based on their similarities.
- The devices have continually proven to be safe and effective and demonstrate intended product performance.

Non-Clinical Tests Submitted:

The Ibramed Powered Muscle Stimulators have been tested in accordance with the applicable standards for medical device electrical safety, electromagnetic compatibility and the particular requirements for stimulator nerve and muscle safety.

EMC-Test

Device Name	Neurodyn Aussie	Neurodyn	Vectra Genisys
K number	121369	121369	031077
Manufacturer	Ibramed	Ibramed	Ibramed
Intended use	Identical	Identical	Identical
Indications for use	Identical	Identical	Identical
Target population	Identical	Identical	Identical
Human factors	Identical	Identical	Identical
Contraindication	Identical	Identical	Identical

The above comparison chart shows that all four devices are identical in every aspect regarding intended use, indications for use, contraindications, target population and human factors

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Device Name	Neurodyn Aussie	Neurodyn	Vectra Genisys
K number	---	---	K031077
Manufacturer	Ibramed	Ibramed	Chattanooga
Technological characteristics Medium-frequency alternating current (MFAC)	Identical	Identical	Identical
Device Material	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display
Width (in)	10.6	14.6	9.75
Height (in)	4.9	4.9	8.75
Depth (in)	10.4	12.4	12.75
Weight (lbs)	4.08	5.5	6
Performance	Identical	Identical	Identical
Biocompatibility	FDA cleared electrodes	FDA cleared electrodes	FDA cleared electrodes
Mechanical safety	Identical	Identical	Identical
Anatomical Sites	Identical	Identical	Identical
Number of channels	4	4	2/4
Russian	No	Yes	Yes
Burst Modulated Alternating Current (Aussie)	Yes	Yes	Yes
Interferential	No	Yes	Yes
Microcurrent	No	Yes	Yes
TENS	No	Yes	Yes
Premodulated	No	Yes	Yes
Voltage Input	100/240V 50/60Hz Bivolt	100/240V 50/60Hz Bivolt	100/240V 50/60Hz 1.0A
Output	+24V 7.3A+24V 7.3A	+24V 7.3A+24V 7.3A	+24V 7.3A+24V 7.3A
Electrical Class	II	II	II
Electrical Type	BF Type	BF Type	BF Type
Method of line current isolation	Double Isolation	Double Isolation	Fuse-Two 5.6A Time Lag
Patient leakage control-normal condition	0.0508mA	0.0508mA	69µA
Patient leakage control-single fault condition	0.0252mA	0.0252mA	31µA

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Software Microprocessor	Yes	Yes	Yes
Automatic overload trip	Yes	Yes	Yes
Automatic shut off	Yes	Yes	Yes
Temperature range during transport and storage	41°F-122°F	41°F-122°F	59°F-104°F
Environment operating temperature range	41°F-113°F	41°F-113°F	59°F-104°F
Locking feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature
Treatment timer	Treatment timer with auto shut off	Treatment timer with auto shut off	Treatment timer with auto shut off
Auto test and repeat	Automatic setting and repeat treatment	Automatic setting and repeat treatment	Automatic setting and repeat treatment
Safety standards requirements	ISO 13485 IEC 60601-1 IEC 60601-2 IEC 60602-10 CE	ISO 13485 IEC 60601-1 IEC 60601-2 IEC 60602-10 CE	ISO 13485 IEC 60601-1 IEC 60601-2 IEC 60602-10 UL 60602
Electromagnetic compatibility	IEC 60601-1-2001/A:2004	IEC 60601-1-2001/A:2004	IEC 60601-1-2001/A:2004

The preceding comparison chart shows that all three devices are similar in every aspect. We assessed the indications for use, intended use, technological characteristics, voltages, inputs, outputs, sizes, weight, types of materials, patient cable construction, software construction, user interface, control parameters, level of concern (software), waveforms, treatment times and the results of each treatment.

We have concluded that the Neurodyn and the Neurodyn Aussie are as safe and effective as the Vectra Genisys. The Ibramed devices deliver the same currents for the same intended uses as the Vectra Genisys. Thus, we found them to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 19, 2012

Ibramed Equipamentos Medicos
% Ms. Lilian Llull
Ibramed U.S. Agent
TechLink International
18851 NE 29th Avenue 720
Aventura, FL 33180

Re: K121369
Trade/Device Name: Neurodyn/Neurodyn Aussie Powered Muscle Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, IPF, LIH, GZI
Dated: November 29, 2012
Received: December 5, 2012

Dear Ms. Llull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Neurodyn Series: Neurodyn/ Neurodyn Aussie

510(k) Number: K121369

As a TENS device:

- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post-surgical acute pain

As an Interferential and Premodulated device:

- Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post traumatic surgical pain

As a Russian device:

- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

As a Burst Modulated Alternating Current (Aussie) device:

- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

As a Microcurrent device:

- Symptomatic relief of chronic intractable pain
- Symptomatic relief of post-traumatic acute pain and post-surgical acute pain

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)
Division of Neurological and Physical Medicine Devices
510(k) Number K121369